

Appln No. 09/711,648
Amdt date May 23, 2011
Reply to Office action of December 21, 2010

REMARKS/ARGUMENTS

In the Final Rejected dated December 21, 2010, the Examiner objects to claims 48-50 as having incorrect status identifiers. Applicant has amended the status identifiers of claims 48-50 to state "Previously Presented." Applicant requests that the objection to claims 48-50 be withdrawn.

The Examiner also maintains the rejection of claims 1-3, 5-20, 23-25, 27, 28, 30-35 and 44-50 under 35 U.S.C. §103(a) as allegedly obvious over Abele, et al. (U.S. Patent No. 5,403,311) in view of West, et al. (U.S. Patent No. 5,318,525) and further in view of Langer, et al. (U.S. Patent No. 6,004,295). In maintaining this rejection, the Examiner argues that Abele teaches a "penetration monitoring electrode (26) mounted on the injection needle." Office action, page 3 (citing col. 3, lines 25-52; col. 4, lines 19-29; and col. 5, lines 53-55 of Abele). The Examiner appears to construe the probe 24 as the recited injection needle and the electrode ring 26 as the recited penetration monitoring electrode. However, none of the cited passages describes the electrode ring 26 as being *fixedly mounted* on the probe 24.

As stated in col. 5, lines 49-50 and shown in FIG. 2 of Abele, the "electrode ring assembly 26 [is] on distal end 22 of catheter body 28." Additionally, the "probe 24 is slidably supported within the catheter body 28 and can be adjusted axially in or out" (col. 5, lines 57-59), such that the "probe 24 is projectable and retractable from catheter body 28" (col. 6, lines 16-17). In particular, as shown in FIGS. 3A and 3B, "after electrocoagulation, the small electrode probe 24 is pulled back into catheter body 28." Abele, col. 8, lines 6-8. As can be seen in FIG. 3B, when the probe 24 is pulled back into the catheter body 28, the electrode ring 26 remains on the distal end of the catheter body 28. Accordingly, the ring electrode 26 does not appear to be fixedly mounted on the probe 24 as recited in independent claims 1, 9, and 23.

Moreover, the Examiner appears to concede on page 4 of the present Office action and page 3 of the May 28, 2010 Office action that "Abele does not teach a puller wire and deflection control handle for controlling the deflection of the tip section *or the penetration monitoring electrode fixedly mounted on the needle tip.*"

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The Examiner asserts that Langer makes up for the deficiencies of Abele by teaching “an injection needle which slides in and out of a catheter (Fig 4A-4C) which may have a penetration monitoring electrode (80, Fig 8A) fixedly mounted on the needle.” Office action, page 4 (citing col. 8, lines 20-35 of Langer). In the cited passage, Langer teaches the “recording electrode 80 in the form of a ring around the *distal, penetrating end* of needle 36” (col. 8, lines 22-23). Langer does not explicitly disclose that the recording electrode 80 is fixedly mounted on the needle. However, even assuming *arguendo* that the recording electrode 80 is fixed (which Applicant does not concede), Langer does not disclose, teach, or suggest that the recording electrode 80 is “electrically insulated” from the needle 36, as recited in independent claims 1, 9, and 23.

Moreover, those of ordinary skill in the art would not have found any reason to place the recording electrode 80 of Langer around the distal, penetrating end of the probe 24 of Abele. Abele teaches that “the coaxial probe 24 is injected to penetrate the tissue site...[and] the electrode ring 26 is moved relatively forward until the appropriate depth separation between probe tip and catheter body tip is obtained, with electrode ring 26 engaged upon the surface of the tissue.” Abele, col. 6, lines 52-60. As such, the electrode ring 26 appears to be mounted on the catheter body 28 so as to stop further penetration of the probe 24, by engaging with the surface of the tissue when the probe 24 reaches the appropriate depth of penetration in the tissue. If, as suggested by the Examiner (*see* Office action, page 4), the recording electrode 80 of Langer was fixedly mounted on the probe 24 of Abele around the distal, penetrating end of the probe as taught by Langer (*see* Langer, col. 8, lines 22-23), the recording electrode 80 would not be able to stop further penetration of the probe 24 by engaging upon the surface of the tissue, as taught in Abele.

Therefore, neither Abele nor Langer, alone or in combination, teach or suggest a penetration monitoring electrode that is fixedly mounted on the injection need *and* electrically insulated from the injection needle, as recited in independent claims 1, 9, and 23. West does not appear to remedy these deficiencies of Abele and Langer. As such, independent claims 1, 9 and

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23, and all claims dependent therefrom, including claims 2, 3, 5-8, 10-20, 24-28, 30-35 and 44-50, are allowable over Abele, West and Langer.

With respect to method claims 12, 13, 15, 17, 18, 20, 30-35, 44, 45, and 47, the Examiner contends that "Abele describes various potential methods of use, disclosing all of the claimed methods." Office action, page 5 (citing "Summary of the Invention" and "Description of Preferred Embodiments" of Abele). Claims 12, 13, 15, 17, 18, 20, 30-35, 44, 45, and 47 are allowable by virtue of their dependency from allowable base claims. Nevertheless, in an effort to expedite allowance of this application, Applicant has amended claims 12, 17, 30, 32, 34, and 44 to include the limitation of "using the penetration monitoring electrode fixedly mounted on the injection needle." As discussed above, Abele, Langer, and West fail to teach or suggest these features.

Applicant also maintains that Abele nowhere teaches or suggests a method in which a determining step comprises measuring the impedance across the electrode mounted on the injection needle, as recited in claim 45, or a method in which a determining step comprises comparing the impedance across the electrode mounted on the injection needle to the impedance across the additional electrode, as recited in claims 20 and 47.

The Examiner responds that "Abele teaches (Col 9, line 54-Col 10, line 45), that the device is used for mapping heart function which is well known in the art to use comparisons of impedances to detect contact with fluid or tissue." Office action, page 6. In the cited passage, however, Abele discloses only that "the electrical condition is sensed between the electrodes." Abele does not describe using comparisons of impedances.

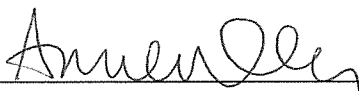
As explained in MPEP Section 2144.03, "[i]t is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based." In re Zurko, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). Also, "[i]f the examiner is relying on personal knowledge to support the finding of

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what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding.” As the Examiner has not provided any “concrete evidence” in support of his assertion that it “is well known in the art to use comparisons of impedances to detect contact with fluid or tissue,” Applicant respectfully requests withdrawal of this rejection of claims 12, 13, 15, 17, 18, 20, 30-35, 44, 45, and 47.

Claims 1-20, 23-28, 30-35 and 44-50 are pending in this application. By this amendment, Applicant has amended claims 12, 17, 30, 32, 34, and 44 to place the claims in condition for allowance. The amendments find full support in the original specification, claims and drawings, and no new matter is presented. In light of the above amendments and remarks, Applicant submits that all of pending claims 1-20, 23-28, 30-35 and 44-50 are in condition for allowance. Applicant therefore respectfully requests reconsideration and a timely indication of allowance. However, if there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact Applicant's counsel at the number indicated below.

Respectfully submitted,
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